

REMARKS

The outstanding Office Action addresses claims 1-23. Applicant appreciates the Examiner's allowance of claims 17-23. Applicant submits, however, that all claims represent allowable subject matter, and reconsideration and allowance thereof is respectfully requested.

Amendments to the Claims

Applicant amends claim 1 to move the language relating to the blocking element, such that the blocking element is more positively recited, as required by the Examiner.

No new matter is added.

Objections to the Drawings

The Examiner objects to the drawings pursuant to 37 C.F.R. §1.83(a), arguing that the drawings do not show every feature of the invention. Specifically, the Examiner requires drawings illustrating the flexible bellows, programmable spring mechanism, leaf spring, coil spring, and helical spring, as recited in claims 11-14.

At the outset, Applicant notes that a flexible bellows is shown in FIG. 2, and therefore a further drawing is not necessary. With regard to the remaining features, Applicant respectfully disagrees with the Examiner's request for drawings, and submits that drawings are not necessary. 35 U.S.C. §113, first sentence, states that an "applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented." Programmable spring mechanisms, leaf springs, coil springs, and helical springs are well known in the art, and drawings showing such features are not necessary for the understanding of the invention. Reconsideration and withdrawal of this requirement is therefore respectfully requested.

Rejections Pursuant to 35 U.S.C. §112

Claims 1-3 and 15 are rejected pursuant to 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that the "blocking element" recited in claim 1 is not positively

recited, and therefore there is insufficient antecedent basis for this limitation in claims 2, 3, and 15. Applicant respectfully disagrees, as claim 1 clearly recites that the biasing element “exerts a force against a first surface of *a blocking element*, the blocking element being configured to seat against the opening to prevent fluid flow therethrough.” However, in order to further prosecution, Applicant amends claim 1 to separately recite a blocking element, thereby overcoming the Examiner’s rejection. Withdrawal of this rejection is therefore respectfully requested.

Rejections Pursuant to 35 U.S.C. §103(a)

Claims 1-3 and 11-16 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,437,627 of Lecuyer in view of U.S. Patent No. 4,787,886 of Cosman. The Examiner argues that Lecuyer discloses the shunt system substantially as claimed, but admits that Lecuyer does not teach a pressure sensor. Thus, the Examiner relies on Cosman to disclose a pressure sensor for measuring pressure outside the heart, arguing that it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the shunt of Lecuyer to include a pressure sensor, as taught by Cosman, “to ensure that the drainage is proper.” (Office Action, page 4.) Applicant respectfully disagrees.

At the outset, neither Lecuyer nor Cosman teach or even suggest a valve having a blocking element with an area on a first surface exposed to the biasing force that is substantially equal to an area on a second surface exposed to the countervailing pressure, as required by claim 1. This feature is illustrated, for example, in Figure 2 of the present application, and as shown the area 64 on the blocking element 60 that is exposed to the intracranial pressure is substantially equal to the area 62 on the blocking element 60 that is exposed to the biasing element 58. As a result, the valve is inherently anti-siphoning. Neither Lecuyer or Cosman teach or even suggest such a feature. As shown in Figure 1 of Lecuyer, the flow orifice (22) in the valve is in communication with an area on the ball (26) that is significantly less than the area on the opposed side of the ball (26) that is exposed to the spring (30). Cosman likewise does not teach the claimed invention, and in fact Cosman fails to teach or even suggest any type of blocking element. Rather, the valve merely includes a port that is in communication on one side with a pressure sensor positioned subcutaneously, and that is blocked on the other side by a flexible diaphragm that measures pressure at the surface of the brain. When the diaphragm moves outward, the port is open to allow fluid to flow therethrough. Cosman thus

does not include any type of blocking element in the port, or if the flexible diaphragm is considered to be a blocking element, then Cosman fails to include a biasing element. Accordingly, neither Lecuyer nor Cosman teach or even suggest the claimed invention, and therefore claims 1-3 and 11-16 distinguish over these references and represent allowable subject matter.

Claims 1-3 and 11-16 further distinguish over Lecuyer and Cosman because it would not have been obvious to a person having ordinary skill in the art at the time of the invention to modify the valve of Lecuyer to include a pressure sensor as taught by Cosman. Lecuyer *already* discloses a pressure sensor. As shown in Figure 1, Lecuyer discloses an implantable hydrocephalus valve that includes a housing having a chamber that is separated into two regions by a flexible diaphragm (16). The first region (18) is associated within an inflow port (34) in the valve and it is maintained at a subcutaneous pressure by pressure-equalizing apertures (42a, 42b) formed in the housing, and the second region (20) is associated with an outflow port (44) in the valve and it is thus maintained at the pressure of the drainage location within the body. A fluid flow orifice (22) is formed in the flexible diaphragm (16) and it defines a seat (26) for receiving a ball (28). The ball (28) is retained within the seat under the force exerted by a compression spring (30) onto the ball (28). In use, the diaphragm functions as a pressure sensor. “Variations in the pressure differential across the valve caused by changes in the fluid column height, such as when the patient arises from a lying or recumbent position, are compensated for by the action of the flexible diaphragm.” (Lecuyer, Col. 2, lines 17-21.) In particular, when the patient stands up causing a siphoning effect, the excess pressure that would normally be exerted on the ball causing the valve to open instead causes the diaphragm to flex while the ball remains firmly seated in the valve seat. The valve therefore “prevents excess drainage of CSF in the event of normal increases in differential fluid pressures” (Lecuyer, Col. 3, lines 2-5.) Since Lecuyer provides a valve having a pressure sensor, i.e., a flexible diaphragm, that ensures “that the drainage is proper,” it would not have been obvious to modify the valve of Lecuyer to include a pressure sensor, such as the pressure sensor disclosed by Cosman. Claims 1-3 and 11-16 are therefore not obvious over Lecuyer in view of Cosman.

Applicant further notes that the pressure sensor of Cosman cannot simply be combined with the valve of Lecuyer to arrive at the present invention. The pressure sensor disclosed by Cosman is a flexible diaphragm that is formed on an external surface of the valve and it is designed to measure

pressure at the surface of the brain. Movement of the diaphragm opens and closes the valve port to control fluid flow therethrough. The flexible diaphragm sensor cannot simply be added to the Lecuyer valve, as it would interfere with the ball and biasing spring that controls the flow of fluid through the port. Also, the diaphragm of Cosman would affect the proper functioning of the valve and the equilibrium established between the two chambers by the existing flexible diaphragm.

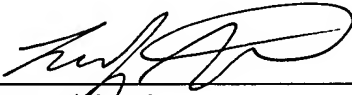
Accordingly, claims 1-3 and 11-16 distinguish over and are not obvious in view of Lecuyer and Cosman, and therefore there claims represent allowable subject matter.

Conclusion

In view of the remarks above, Applicant submits that all claims are in condition for allowance. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

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